

Title: IMPLANTABLE STIMULATION LEAD WITH FIXATION MECHANISM

Inventors: Gerber and Swoyer

Docket No.: P9492.00

CLAIMS:

1. A neurostimulation lead comprising:
a lead body having a proximal end and a distal end;
one or more stimulation electrodes disposed adjacent the distal end of the lead body;
and
a fixation mechanism mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, the fixation mechanism including one or more wire-like elements that are expandable to fix the lead body at a tissue target site.
2. The neurostimulation lead of claim 1, wherein each of the wire-like elements includes an elastic material.
3. The neurostimulation lead of claim 1, each of the wire-like elements having a proximal joint where the proximal end of the wire-like element meets the lead body, and a distal joint where the distal end of the wire-like element meets the lead body, wherein the distal joint is weaker than the proximal joint.
4. The neurostimulation lead of claim 1, wherein each of the elastic wire elements includes a shape memory alloy.
5. The neurostimulation lead of claim 1, wherein each of the wire-like elements includes a super-elastic material.
6. The neurostimulation lead of claim 4, wherein the shape memory alloy includes Nitinol.
7. The neurostimulation lead of claim 1, further comprising an inner lumen to accommodate a stylet.

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8. The neurostimulation lead of claim 1, further comprising a restraint mechanism to restrain the wire-like elements against expansion, wherein the wire-like elements expand upon removal of at least part of the restraint mechanism.
9. The neurostimulation lead of claim 8, wherein the restraint mechanism includes a lead introducer, the lead introducer defining a lead introducer lumen sized to accommodate the stimulation lead body.
10. The neurostimulation lead of claim 8, wherein the restraint mechanism includes a stylet, the stylet accommodated by an inner lumen of the neurostimulation lead.
11. The neurostimulation lead of claim 1, wherein at least a portion of the lead body is elastic, causing a diameter of the lead body portion to decrease when the lead body portion is stretched.
12. The neurostimulation lead of claim 1, wherein each of the wire-like elements is configured in a substantial helical shape.
13. The neurostimulation lead of claim 1, further comprising retainer rings mounted about the lead body to retain opposite ends of each of the wire-like elements.
14. The neurostimulation lead of claim 1, wherein one of the wire-like elements acts as an electrode for neurostimulation current.
15. The neurostimulation lead of claim 1, wherein the one or more electrodes include at least four electrodes.
16. The neurostimulation lead of claim 1, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 2 to 10 mm.

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17. The neurostimulation lead of claim 1, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 4 to 6 mm.
18. The neurostimulation lead of claim 1, wherein the of the fixation mechanism is sized to be expandable to a diameter in a range of approximately 6 to 15 mm.
19. The neurostimulation lead of claim 1, wherein the of the fixation mechanism is sized to be expandable to a diameter in a range of approximately 9 to 12 mm.
20. The neurostimulation lead of claim 1, wherein the stimulation lead includes radio-opaque material that is detectable by fluoroscopic imaging.
21. The neurostimulation lead of claim 1, wherein the lead is one of a sacral lead, a pudendal nerve lead, and a spinal cord stimulation lead.
22. A neurostimulation system comprising:
 - an implantable neurostimulation pulse generator;
 - a lead body having a proximal end and a distal end;
 - one or more stimulation electrodes disposed adjacent the distal end of the lead body;
 - an electrical conductor to electrically couple the implantable neurostimulation energy generator to a number of the electrodes; and
 - a fixation mechanism mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, the fixation mechanism including one or more wire-like elements that are expandable to fix the lead body at a tissue target site.
23. The neurostimulation system of claim 22, wherein each of the wire-like elements includes an elastic material.
24. The neurostimulation system of claim 22, each of the wire-like elements having a proximal joint where the proximal end of the wire-like element meets the lead body, and a

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distal joint where the distal end of the wire-like element meets the lead body, wherein the distal joint is weaker than the proximal joint.

25. The neurostimulation system of claim 22, wherein each of the elastic wire elements includes a shape memory alloy.

26. The neurostimulation system of claim 22, wherein each of the wire-like elements includes a super-elastic material.

27. The neurostimulation system of claim 25, wherein the shape memory alloy includes Nitinol.

28. The neurostimulation system of claim 22, further comprising an inner lumen to accommodate a stylet.

29. The neurostimulation system of claim 22, further comprising a restraint mechanism to restrain the wire-like elements against expansion, wherein the wire-like elements expand upon removal of at least part of the restraint mechanism.

30. The neurostimulation system of claim 29, wherein the restraint mechanism includes a lead introducer, the lead introducer defining a lead introducer lumen sized to accommodate the stimulation lead body.

31. The neurostimulation system of claim 29, wherein the restraint mechanism includes a stylet, the stylet accommodated by an inner lumen of the neurostimulation lead.

32. The neurostimulation system of claim 22, wherein at least a portion of the lead body is elastic, causing a diameter of the lead body portion to decrease when the lead body portion is stretched.

33. The neurostimulation system of claim 22, wherein each of the wire-like elements is configured in a substantial helical shape.
34. The neurostimulation system of claim 22, further comprising retainer rings mounted about the lead body to retain opposite ends of each of the wire-like elements.
35. The neurostimulation system of claim 22, wherein one of the wire-like elements acts as an electrode for neurostimulation current.
36. The neurostimulation system of claim 22, wherein the electrodes include at least four electrodes.
37. The neurostimulation lead of claim 22, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 2 to 10 mm.
38. The neurostimulation lead of claim 22, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 4 to 6 mm.
39. The neurostimulation lead of claim 22, wherein the of the fixation mechanism is sized to be expandable to a diameter in a range of approximately 6 to 15 mm.
40. The neurostimulation lead of claim 22, wherein the of the fixation mechanism is sized to be expandable to a diameter in a range of approximately 9 to 12 mm.
41. The neurostimulation system of claim 22, wherein the stimulation lead includes radio-opaque material that is detectable by fluoroscopic imaging.
42. A method comprising:
inserting a lead introducer into a patient;
inserting a lead into the patient via the introducer, wherein the lead includes a lead body having a proximal end and a distal end, one or more stimulation electrodes disposed on

the lead body, and a fixation mechanism mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, the fixation mechanism including one or more wire-like elements that are expandable to fix the lead body at a tissue target site; and

removing a restraint mechanism on the fixation mechanism, thereby permitting the wire-like elements to expand.

43. The method of claim 42, wherein removing a restraint includes withdrawing at least part of a stylet from a lumen of the lead, thereby releasing the fixation mechanism to expand.

44. The method of claim 42, wherein removing a restraint includes withdrawing at least a portion of the lead introducer, thereby releasing the fixation mechanism to expand.

45. The method of claim 42, further comprising:
detaching a distal end of each wire-like element; and
withdrawing the lead from the target site.

46. The method of claim 42, further comprising:
restraining the expanded fixation mechanism; and
withdrawing the lead from the target site.

47. The method of claim 42, wherein the restraint mechanism includes a lead introducer, the lead introducer defining a lead introducer lumen sized to accommodate the stimulation lead body.

48. The method of claim 42, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 2 to 10 mm.

49. The method of claim 42, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 4 to 6 mm.

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50. The method of claim 42, wherein the of the fixation mechanism is sized to be expandable to approximately a diameter in a range of approximately 6 to 15 mm.

51. The method of claim 42, wherein the of the fixation mechanism is sized to be expandable to approximately a diameter in a range of approximately 9 to 12 mm.

52. The method of claim 42, wherein each of the wire-like elements includes an elastic material.

53. A stimulation lead comprising:
a lead body having a proximal end and a distal end;
one or more stimulation electrodes disposed on the lead body; and
means for fixing the lead body relative to tissue proximate a target stimulation site,
wherein the fixing means includes wire-like elements that are expandable to fix the lead body at a tissue target site.

54. The lead of claim 53, wherein each of the wire-like elements includes an elastic material.

55. The lead of claim 53, each of the wire-like elements having a proximal joint where the proximal end of the wire-like element meets the lead body, and a distal joint where the distal end of the wire-like element meets the lead body, wherein the distal joint is weaker than the proximal joint.

56. The lead of claim 53, wherein each of the elastic wire elements includes a shape memory alloy.

57. The lead of claim 53, wherein each of the wire-like elements includes a super-elastic material.

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58. The lead of claim 53, further comprising means for restraining the wire-like elements against expansion, wherein the wire-like elements expand upon removal of at least part of the restraining means.

59. The lead of claim 53, wherein the lead is one of a sacral lead, a pudendal nerve lead, and a spinal cord stimulation lead.